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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,268	07/25/2001	Brad T. Bosworth	21419/91513	9905

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EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/844,268

Applicant(s)

BOSWORTH ET AL.

Examiner

Joseph T. Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2,4,6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,4,6 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This application filed April 27, 2001 is a continuation of 09/443,766 filed November 19, 1999, which claims benefit under 35 U.S.C. 120 to PCT/US98/10318, filed May 20, 1998, which claims benefit to provisional application 60/047,181, filed May 20, 1997.

Applicants amendment filed September 30, 2005, has been received and entered. Claims 1, 3, 5-11 have been canceled. Claims 2, 4 and 6 have been amended. Claims 2, 4, 6 and 7 are pending and currently under examination.

Upon review of the pending claims, a new grounds of rejection is being made. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a).

### ***Claim Objections***

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, claim 6 appears to be directed to a separate and unique nucleic acid sequence than that of claim 2. Alternatively, claim 2 would have to be interpreted as encompassing effectively any derivative of SEQ ID NO: 12 beyond the single

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altered base at position 307, which does not seem reasonable in light the claim language nor the specific teachings of the present specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 6 and 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The cancellation and amendment to the claims have addressed the basis of each of the specific rejections previously made of record.

Claims 2 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claim is confusing and unclear as it is drawn to an additional alteration in SEQ ID NO: 12. Initially, it is noted that sequences encompassed by t claim 2 do not even require that position 229 be present. However, if present, there is no indication that any other nucleotide in SEQ ID NO: 12 besides position 307 would be altered. It is unclear if claim 2 encompasses any alteration or derivative of SEQ ID NO: 12, and if not, how claim 6 would be considered further limiting (as discussed above in the claim objection).

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

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invention. Specifically, the claim is indefinite in the recitation and embodiments encompassed by “distinguishes” because what or how this is performed is not clearly set forth in the claim nor the specification. The metes and bounds of the claim are unclear because they are dependent and relative to the methodology used to “distinguish” resistance.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Larsen *et al.* (1990))(as evidenced by Meijerink *et al.*, 1997).

Claim 4 simply requires a sequence that is complimentary to SEQ ID NO: 12, and similarly claim 7 requires only a sequence that can be used to identify SEQ ID NO 12 to distinguish resistance. Neither claim requires a sequence that is unique from SEQ ID NO: 12. Larsen *et al.* teach the isolation of a cDNA encoding human FUT 1 and provide the specific sequences (see figure 3), which comprises sequence that are homologous to SEQ ID NO: 12 (see for example figure 3A of Meijerink *et al.*). Clearly, the human sequence could be used as a basis of comparison and represents fragments of sequences that could be used as primers to evaluate SEQ ID NO: 12. With respect to sequences that are complimentary, the disclosure that the sequence was obtained as a cDNA provides support for the disclosure of the complimentary sequence of the coding sequence depicted in Figure 3.

Claims 2, 4, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5,474,796- issued Dec 1995).

The breadth of claims 4 and 7 are summarized above. Claim 2 is drawn to a sequence that comprises an adenine at position 307, encompasses a sequence of any size even adenine itself, or a tri-nucleotide such as ACG (where this represents bp 307-309 of SEQ ID NO: 12). Similarly, claim 6 only requires that base pair 229 is a thymine, with no specific requirement on the size/length of the DNA molecule. Brennan disclose oligonucleotide DNA sequences (see for example column 5, first paragraph), and reduce to practice providing 10mers representing every possible permutation of a sequence. While there is not a specific disclosure of SEQ ID NO: 12, nor one the has an adenine or thymine substitution, clearly providing sequences of every permutation provides for multiple fragments that would anticipate the breadth of the instant claims.

### ***Conclusion***

No claim is allowed.

The art indicates that cell surface receptors on intestinal cells are the target molecules for *E. coli* colonization, and that the glycosylation on said receptors may be important in determining the ability of a particular *E. coli* to colonize the intestine. However, the art fails to specifically teach that an adenine at position 307 of the open reading frame of alpha (1,2) fucosyltransferase (FUT1) (SEQ ID NO: 12) can be correlated with resistance to *E. coli* strain

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F18 and possibly with the subsequent associated diseases. However, the breadth of the claims are directed to products which were disclosed in the prior art

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

*Joseph T. Woitach*  
AUG 31